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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/853,854	05/11/2001	Donna M. Crabb	P50953D1	7155

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EXAMINER	
DELACROIX MUIRHEI, CYBILLE	

ART UNIT	PAPER NUMBER
1614	12

DATE MAILED: 10/03/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/853,854	CRABB ET AL.	
	Examiner	Art Unit	
	Cybille Delacroix-Muirheid	1614	

-- The MAILING DATE of this communication app ars on the c ver sheet with the correspond nce address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 June 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *3,8 and 12-34* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *3,8 and 12-34* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 9 .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

Detailed Action

The following is responsive to the request for continued examination and the IDS received June 3, 2002.

No claims are cancelled. No new claims are added. Claims 3, 8, 12-34 are currently pending.

Information Disclosure Statement

Applicant's Information Disclosure Statement received June 3, 2002 has been considered. Please refer to Applicant's copy of the 1449 submitted herewith.

Claim Rejection—35 USC 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein

were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

1. Claims 3, 8, 12-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over the Hannan et al. (abstract) (submitted by Applicant in the IDS of June 3, 2002) in view of Kim et al. WO 9842705 (already of record).

Hannan et al. disclose that SB-265805, also known as gemifloxacin mesylate (please see specification, page 1, line 11), demonstrated excellent *in vitro* activity against the *Mycoplasma* and *Ureaplasma* species of bacteria. The specific species tested were *Ureaplasma urealyticum, M. pneumoniae, M. fermentans, M. penetrans, M. hominus and M. genitalium* .The MIC range used was 0.001-0.25 microgram/ml, which is "well within the range of expected clinical susceptibility." Hannan et al. concludes by teaching that the results indicate that gemifloxacin mesylate has excellent broad spectrum antimycoplasmal activity, and that the compound should be extremely effective in treating respiratory and urogenital infections caused by *Mycoplasma* spp. Please see the abstract; **MIC Determination**; **Results**, Table 1; **Conclusions**.

Hannan et al. do not specifically disclose a method of treating or preventing mycoplasma induced infection in a mammal by administering an effective amount of gemifloxacin mesylate to the mammal. However, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the *in vitro* methods

of Hannan et al. by administering gemifloxacin mesylate clinically to mammals in need thereof because, in view of the excellent antimycoplasmal properties demonstrated by the *in vitro* tests performed by Hannan et al., one of ordinary skill in the art would reasonably expect gemifloxacin mesylate to exhibit antimycoplasmal activity *in vivo*. In fact, Hannan et al. even suggest that gemifloxacin mesylate would be useful in treating respiratory and urogenital infections caused by *Mycoplasma* spp. (please see again page 32, **Conclusions**). Thus, such a modification would have been motivated by the reasonable expectation that mammals, e.g. humans, infected with or at risk of infection with mycoplasma bacteria would be treated when administered gemifloxacin mesylate.

Additionally, Hannan et al. do not disclose the antibacterial effects of gemifloxacin mesylate sesquihydrate; however, the Examiner refers to Kim et al., which discloses the use of hydrate derivatives of gemifloxacin such as a sesquihydrate derivative of gemifloxacin (hydration number 1.5), in pharmaceutical compositions for treating bacterial infections. Please see Table 1, page 3; page 7, third full paragraph; claims 1-3 and 13.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use gemifloxacin mesylate sesquihydrate to treat or prevent bacterial infections by mycoplasma because Kim et al. disclose that the hydrated derivatives maintain antibacterial activity and in view of the desirable results obtained by Hannan et al., one of ordinary skill in the art would reasonably expect gemifloxacin mesylate sesquihydrate to effectively treat or prevent bacterial infections by the *Mycoplasma* spp.

Finally, concerning the claimed "effective amount" of gemifloxacin administered, since Hannan et al. establish that the MIC range of 0.001-0.25 micrograms/ml would be within the range of expected clinical susceptibility, then based on these numbers, it would have been obvious to one of ordinary skill in the art to arrive at a dosage of gemifloxacin effective to exhibit its antibacterial properties in a mammal thereby treating or preventing bacterial infections by Mycoplasma.

Conclusion

Claims 3, 8, 12-34 are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cybille Delacroix-Muirheid whose telephone number is 703-306-3227. The examiner can normally be reached on Tue-Thur. from 8:30 to 6:00. The examiner can also be reached on alternate Mondays .

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel, can be reached on (703) 308-4725 The fax phone number for the organization where this application or proceeding is assigned is 703-308-7924.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

DWAYNE C. JONES
EXAMINER

CDM

Sep. 30, 2003